

WHAT IS CLAIMED:

1 1. A method for providing an oxygen sensitive container that indicates the presence of  
2 oxygen inside the container, the method comprising:

3           placing an oxygen sensitive material inside a sealable container;  
4           evacuating air from the sealable container and sealing the sealable container to  
5 isolate the oxygen sensitive material from oxygen; and  
6           irradiating the sealable container with an effective amount of radiation to activate  
7 the oxygen sensitive material such that the oxygen sensitive material undergoes a visual  
8 change in the presence of oxygen after the oxygen sensitive material has been irradiated,  
9 the visual change providing an indication of the presence of oxygen inside the sealable  
10 container.

1 2. The method of claim 1, wherein the step of evacuating the air from the sealable container  
2 is performed in a vacuum.

1 3. The method of claim 1, wherein the step of evacuating the air from the sealable container  
2 is performed in a non-oxygen gaseous environment.

1 4. The method of claim 1, wherein the step of irradiating the sealable container uses gamma  
2 radiation to activate the oxygen sensitive material and to sterilize the sealable container and any  
3 contents thereof.

1 5. The method of claim 1, wherein the oxygen sensitive material is a plastic material  
2 comprising a portion of a medical device and the sealable container is a sterile medical container,  
3 and wherein the step of placing the oxygen sensitive material inside the sealable container is  
4 accomplished by placing the medical device inside the sterile medical container such that the  
5 medical device undergoes no visual change until the sterile medical container is opened as long  
6 as no significant amounts of oxygen are present in the sterile medical container prior to the  
7 sterile medical container being opened.

1 6. The method of claim 1, wherein the visual change of the oxygen sensitive material  
2 indicates a failure of the sealable container.

1 7. The method of claim 1, wherein the visual change of the oxygen sensitive material occurs  
2 within 8 hours of exposure to a significant amount of oxygen.

1 8. The method of claim 7, wherein the visual change of the oxygen sensitive material occurs  
2 within 1-2 hours of exposure to the significant amount of oxygen.

1 9. Apparatus for indicating the presence of oxygen comprising:

2 a sealable container that isolates contents of the container from ambient  
3 atmosphere when sealed; and

4 an oxygen sensitive material located within the sealable container, the oxygen  
5 sensitive material being a material that undergoes a visual change when in contact with

6 oxygen once the oxygen sensitive material has been irradiated after the sealable container  
7 has been sealed to activate the oxygen sensitive material.

1 10. The apparatus of claim 9, wherein the oxygen sensitive material comprises at least a  
2 portion of a medical device located within the sealable container such that the medical device  
3 itself is an oxygen indicator.

1 11. The apparatus of claim 9, wherein the oxygen sensitive material comprises a piece of  
2 material fixed inside the sealable container and separate from any other contents of the sealable  
3 container.

1 12. The apparatus of claim 9, wherein the visual change of the oxygen sensitive material  
2 indicates a failure of the sealable container.

1 13. The apparatus of claim 9, wherein the oxygen sensitive material is an oxygen sensitive  
2 polymeric composition.

1 14. The apparatus of claim 13, wherein the oxygen sensitive polymeric composition is a  
2 polycarbonate composition activated by an effective amount of gamma radiation.

1 15. The apparatus of claim 14, wherein the effective amount of gamma radiation is between  
2 about 25 Kilograys to 45 Kilograys.

1     16.     The apparatus of claim 9, wherein the sealable container comprises:

2                     a gas impermeable foil pouch; and

3                     a cardboard protective packaging for the foil pouch.

1     17.     The apparatus of claim 16, wherein the gas impermeable foil pouch is a multi-layer foil  
2     package comprising:

3                     a silicone oxide treated PET layer;

4                     a foil layer;

5                     a biaxially oriented nylon layer; and

6                     a polyethylene layer.

1     18.     The apparatus of claim 9, wherein the oxygen sensitive material is formed as a generally  
2     planar chip of material and is operably positioned adjacent a backing material such that a  
3     combination of the backing material and the planar chip of material increase effective visibility  
4     of the visual change in the oxygen sensitive material over visibility of visual change of the  
5     oxygen sensitive material alone.

1     19.     The apparatus of claim 9, wherein the oxygen sensitive material undergoes the visible  
2     change within less than 8 hours after exposure to a significant amount of oxygen.

1     20.     The apparatus of claim 19, wherein the oxygen sensitive material undergoes the visible  
2     change within 1-2 hours after exposure to a significant amount of oxygen.

1    21.    The apparatus of claim 9, wherein the contents of the container include contents selected  
2    from the set consisting of: a medical device, a drug, a food product, or any combination thereof.

1    22.    The apparatus of claim 9, wherein the oxygen sensitive material is arranged to form at  
2    least one symbol that assists in interpreting the visible change of the oxygen sensitive material.